One Step Ketamine Test Dip Card (Urine) Package Insert

A rapid, one step test for the qualitative detection of Ketamine Metabolite in human urine.
For healthcare professionals including professionals at point of care sites.
For forensic use only.

INTENDED USE

The One Step Ketamine Test Dipcard is a lateral flow chromatographic immunoassay for the detection of Ketamine in human urine:

Test	Calibrator	Cut-off
Ketamine (KET)	Ketamine	1,000 ng/mL

This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1] Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF THE TEST

The One Step Ketamine Test Dip Card is a rapid urine-screening test that utilizes monoclonal antibodies to selectively detect elevated levels of specific drug in urine without the use of an instrument.

Ketamine is a short-acting "dissociative" anesthetic due to its ability to separate perception from sensation. It also has hallucinogenic and painkilling qualities that seem to affect people in very different ways. Ketamine is chemically related to PCP ('Angel Dust'). Ketamine is occasionally administered to people but, more commonly, is used by vets for pet surgery. Generally street K is most often diverted in liquid form from vets' offices or medical suppliers. Ketamine generally takes 1-5 minutes to take effect. Snorted ketamine takes a little longer at 5-15 minutes. Depending on how much and how recently one has eaten, oral ketamine can take between 5 and 30 minutes to take effect. The primary effects of ketamine last approximately an 30-45 minutes if injected, 45-60 minutes when snorted, and 1-2 hours if used orally. The Drug Enforcement Administration reports that the drug can still affect the body for up to 24 hours.

The One Step Ketamine Test Dip Card yields a positive result when the concentration of Ketamine in urine exceeds 1,000 ng/mL.

PRINCIPLE

The One Step Ketamine Test Dip Card is an immunoassay based on the principle of competitive binding. Drugs that may be present in the urine specimen compete against their respective drug conjugates for binding sites on their specific antibody.

During testing, a portion of the urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug Dip Card. The presence of drug above the cut-off concentration in the urine specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the Dip Card because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains a membrane Dip Card coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Ketamine.

PRECAUTIONS

- *For healthcare professionals including professionals at point of care sites.*
- *For professional* in vitro *diagnostic use only. Do not use after the expiration date.*
- *The test Dip Card should remain in the sealed pouch until use.*
- *All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.*
- *Used test Dip Card should be discarded according to federal, state and local regulations.*

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay
The urine specimen must be collected in a clean and dry test container. Urine collected at any time of the day may be used.

Specimen Storage
Urine specimens may be store at 2-8℃(36-46°F) for up to 48hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20℃. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided

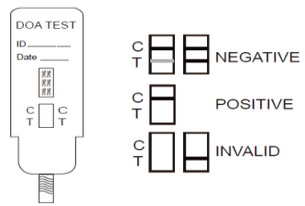
- Test dip card
- Desiccant
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer
- External controls

DIRECTIONS FOR USE

Allow the test device, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.
1) Remove the test device from the foil pouch.
2) Remove the cap from the test device. Label the device with patient or control identifications.
3) Immerse the absorbent tip into the urine sample for 10-15 seconds. Urine sample should not touch the plastic device.
4) Replace the cap over the absorbent tip and lay the device flatly on a non-absorptive clean surface.
5) Read results at 5 minutes.
DO NOT INTERPRET RESULT AFTER 10 MINUTES.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)
NEGATIVE: Two lines appear. * One color line should be in the control region (C), and another apparent red or purple line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.
***NOTE:** The shade of red in the test line region (T) will vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your supplier.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The One Step Ketamine Test Dip Card provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. [3,4,7]
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen and a new test device.
4. A Positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
5. A Negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Reproducibility

Reproducibility studies were carried out using commercially available stork solutions of the drug analytes listed. Dilutions were made from the stork solution of each drug to the concentrations specified in the following tables. The results are listed in the following tables.

Phencyclidine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
1500	40	40 negative	>99%
1500	40	40 positive	>99%
2000	40	40 positive	>99%

Analytical Sensitivity

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below.

KET Concentration (ng/mL)	*Percent of Cut-off*	*n*	*Visual Result*	
			Negative	*Positive*
0	*0*	30	*30*	*0*
500	*-50%*	30	*30*	*0*
750	*-25%*	30	*27*	*3*
1000	*Cut-off*	30	*19*	*11*
1250	*+25%*	30	*1*	*29*
1500	*+50%*	30	*0*	*30*

Analytics Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by One Step Ketamine Test Dip Card at a read time of 5 minutes.

Drug	Concentration (ng/ml)
Ketamine (KET)	
Ketamine	1,000
Norketamine	3,000
Methoxy-amphetamine	12,500
Promethazine	25,000
4 - hydroxyphenyl cyclohexyl piperidine	50,000

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.030) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The One Step Ketamine Test Dipcard was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.0, 4.5, 5.0, 6.0 and 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with The One Step Ketamine Test Dip Card. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reacting

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing Ketamine. The following compounds show no cross-reactivity when tested with the One Step Ketamine Test Dip Card at concentrations of 100 µg/mL.

Non Cross-Reacting Compounds

*Parent compound only.

Acetophenetidin	l-Cotinine	Cortisone	d-Pseudoephedrine
N-Acetylprocainamide	Creatinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Deoxycorticosterone	Labetalol	Quinine
Aminopyrine	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Diclofenac	Meprobamate	Serotonin
Ampicillin	Diflunisal	Methoxyphenamine	Sulfamethazine
l-Ascorbic acid	Digoxin	Methylphenidate	Sulindac
Apomorphine	Diphenhydramine	Nalidixic acid	Tetracycline

Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrocortisone,
Atropine	β-Estradiol	Niacinamide	3-Acetate
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tetrahydrocortisone
Benzoic acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
d,l-Brompheniramine	Furosemide	d,l-Octopamine	Thioridazine
Caffeine	Gentisic acid	Oxalic acid	d,l-Tyrosine
Cannabidiol	Hemoglobin	Oxolinic acid	Tolbutamide
Chloralhydrate	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Penicillin-G	Trimethoprim
d,l-Chlorpheniramine	o-Hydroxyhippuric acid	Perphenazine	d,l-Tryptophan
Chlorpromazine	3-Hydroxytyramine	Phenelzine	Uric acid
Cholesterol	d,l-Isoproterenol	Prednisone	Verapamil
Clonidine	Isoxsuprine	d,l-Propanolol	Zomepirac

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